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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/578,661	05/08/2006	Gerhard Hartwich	212/856US	6770

23371 7590 01/24/2008
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EXAMINER

LAM, ANN Y

ART UNIT	PAPER NUMBER
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1641

MAIL DATE	DELIVERY MODE
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01/24/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/578,661	Applicant(s) HARTWICH, GERHARD	
	Examiner Ann Y. Lam	Art Unit 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 May 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) 24-26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/ are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>5/8/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-23, drawn to a substrate, classified in class 435, subclass 287.2
- II. Claims 24-26, drawn to a method for detecting a ligate-ligand association event, classified in class 436, subclass 518.

Inventions I and II are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another and materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the apparatus as claimed can be used to practice another and materially different process such as purification, or synthesis of biomolecules.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required

because the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

During a telephone conversation with David Crockett on December 18, 2007, a provisional election was made without traverse to prosecute the invention of group I, claims. Affirmation of this election must be made by applicant in replying to this Office action. Claims 124-26 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

It is noted that a species election requirement between the concentration and surface area was also made during the telephone conversion and Applicant's attorney elected the species surface area. However, both species were coincidentally found during the search and thus there does not appear to be a serious burden on Examiner to prosecute both species at this point.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States

only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2, 13-20, 22 and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Hubbell et al., 6,884,628.

Hubbell et al. disclose simultaneous determination of multiple analytes in one or more liquid samples, wherein the patterned surface is used in microarray assays for the determination of analytes of antibodies or antigens and DNA for example, and that detection of specific areas of the pattern can be localized to the specific areas or can be performed for multiple specific areas simultaneously (col. 31, lines 43-51). The substrate is disclosed for example in column 10, lines 4 and line 45. Hubbell et al. teach for example fluorescence labeling for detection of the analyte (col. 16, lines 1-6.)

Hubbell et al. also teach that the type of ligand is chosen according to the needs of the analytical or sensing task (col. 10, lines 13-15). Hubbell et al. also teach ligands that are able to bind specifically to a bioactive recognition moiety, the recognition units being for example antigens, proteins and oligonucleotides, provided they are able to interact specifically with the analyte in the subsequent analytical or sensing assay (col. 10, lines 61-66). (In this example, the ligand binds the recognition moiety, which binds to an analyte). Hubbell et al. also teach that for example an antibody may be biotin-conjugated and adsorbed to a streptavidin-functionalized surface (col. 16, lines 1-3).

Thus, Hubbell et al. teach using a microarray for simultaneous assays for different analytes, the analytes being for example proteins or oligonucleotides, and thus different probes are used.

The substrate of the array is equivalent to Applicant's substrate, and the loading parameter that permits detection of the ligands is any part of the substrate carrying the immobilized recognition moiety because Applicant has not specified elements that comprise the loading parameter.

As to claim 2, the substrate inherently has a surface area.

As to claims 13-16, the concentration is not positively recited as part of the claimed invention, i.e., the substrate, and thus the limitations regarding concentration relates to intended use and the Hubbell et al. substrate is capable of detecting the various concentration ranges claimed.

As to claims 17-19 and 22, use of antibodies or antigens or enzymes or their ligands as the ligates for the detection of one of the other using the Hubbell et al. substrate is within the skills of the ordinary artisan as such biomolecules are well known recognition moieties for the detection of their binding partners (see Hubbell for example, col. 31, lines 43-53).

As to claim 23, the upper portion of the substrate is equivalent to the recited passivation layer.

Claims 1, 2, 9, 13-19, 22 and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Leproust et al. , 20040151635.

As to claims 1 and 9, Leproust et al. teach an array with multiple regions of different moieties, such as different polynucleotide sequences, such that a region, or spot, of the array will detect a particular target (paragraph 0028). Moreover, Leproust et al. also teach forming an array with features of different probe composition in a region which features are repeated in another region but with a different probe density (paragraph 0075)..

As to claim 2, the substrate inherently has a surface area.

As to claims 13-16, the concentration is not positively recited as part of the claimed invention, i.e., the substrate, and thus the limitations regarding concentration relates to intended use and the Leproust et al. substrate is capable of detecting the various concentration ranges claimed.

As to claims 17-19 and 22, use of antibodies or antigens or enzymes or their ligands as the ligates for the detection of one of the other using the Leproust et al. substrate is within the skills of the ordinary artisan as such biomolecules are well known recognition moieties for the detection of their binding partners and Leproust et al. suggest providing an array to detect various target analytes such as proteins (paragraph 0048).

As to claim 23, the upper portion of the substrate is equivalent to the recited passivation layer.

Claim 3 is rejected under 35 U.S.C. 102(e) as being anticipated by Abbott et al., 20040038408.

Abbott et al. teach an assay substrate having a gradient in topography across its surface for use in increasing the dynamic range of detection of analytes or for detecting the presence of analytes of a different size within a sample (paragraph 0100). Abbott et al. also teach that recognition moieties may be arrayed on the substrate surface in any appropriate configuration, including a variety of different antibodies, polypeptides or polynucleotides arrayed in spots that are in proper alignment to be read by a reader (paragraph 0300). While they are disclosed separately in the patent, it is understood that the invention encompasses a substrate with a gradient of topographies with different recognition moieties in discrete spots because Abbott et al. disclose that one purpose of the gradient in topography is to detect analytes of different sizes, and different analytes generally require different recognition moieties. The different topographies inherently have different surface areas.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 20 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hubbell et al., 6,884,628, in view of Ewart et al., 5,922,537

Hubbell et al. teach the invention substantially as claimed except for the analyte being a hormone or its receptor. Ewart et al. teach that an analyte may be any of a variety of substance including a hormone (col. 7, lines 57-64.) The skilled artisan would recognize the desirability of detecting a hormone or its receptor, using one or the other of the binding partner, using the Hubbell et al. substrate, as such substrate is not limited to any particular recognition moiety but rather Hubbell et al. teach that any of a variety of binding partners may be used.

Claims 10-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leproust et al., 20040151635.

Leproust et al. teach the invention substantially as claimed (see above), except for the difference in the loading density of the test sites as recited by Applicant (i.e., by a factor of 10, 100 or 500). However, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. (MPEP 2144.05 IIA, citing *In re Aller*, 105 USPQ 233). In this case, the difference in loading density of the test sites as recited by Applicant is within a workable range and thus its discovery involves only routine skill in the art.

Claims 4-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Abbott et al., 20040038408.

Abbott et al. disclose the invention substantially as claimed (see above).

As to claims 4-6 however, Abbott et al. do not disclose the specific difference in surface area as recited by Applicant (differing by a factor of 10, 100, 1000, or 10,000). However, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. (MPEP 2144.05 IIA, citing *In re Aller*, 105 USPQ 233). In this case, as suggested by Abbott et al., the different topographies are useful for detecting different analytes (paragraph 0300), and thus providing topographies that differ by the factors recited by Applicants fall within workable ranges as would be necessary for particular analytes having specific differences in sizes.

As to claims 7-8, Abbott et al. do not disclose the surface area of the substrate being in the range recited by Applicants (between 1 μm^2 to 10 mm^2 or 10 μm^2 to 100,000 μm^2). However, Abbott et al. do disclose that the substrate surface may be prepared by rubbing, nanoblasting (i.e., abrasion of a surface with submicron particles to create roughness) or oblique deposition of a metal (paragraph 0075). While the gradient in topography is disclosed in general, there is no disclosure as to the surface area or size of the test sites. However, given the disclosure regarding nanoblasting, it is understood that the surface roughness is small in scale. Moreover, the ranges in


surface area of the test site as recited by Applicant are within a workable range and thus involves only routine skill in the art.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Y. Lam whose telephone number is 571-272-0822. The examiner can normally be reached on Mon.-Fri. 10-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Ann Y. Lam
Primary Patent Examiner